COVID-19 Therapeutics Information Brief

April 6, 2022

Changes to the document from the previous version are highlighted in yellow.

The next Therapeutics Information Brief will be April 20, 2022.

IMPORTANT/NEW COVID-19 Therapeutics Information

- Sotrovimab is NO Longer Authorized to Treat COVID-19 Vaccine in any U.S. Region
- Evusheld Fact Sheet Updated
- HRSA COVID-19 Uninsured Program and HRSA COVID-19 Coverage Assistance Fund
- COVID-19 Outpatient Therapeutics Clinical Decision Aid for Ages 12+
- COVID-19 Test to Treat Locator
- Molnupirair EUA Updated to a trade name Lagevrio
- Sotrovimab Effectiveness Against Omicron Subvariant BA.2
- Shelf Life Extension for Sotrovimab
- Return of bam/ete and REGEN-COV NOT Recommended
- Guidelines for Product Return
- CMS Updates: Coding for 600 mg Evusheld
- CMS Updates Codes for Bebtelovimab and Remdesivir
- Reporting Evusheld Doses in HPoP
- Allocation Cadence Changes for Monoclonal Antibodies, Pre-Exposure Prophylaxis Treatment and Antivirals
- Therapeutic Reporting Reminder
- Reporting Wastage Guidance
- Allocations Remaining for Monoclonal Antibodies, Pre-Exposure Prophylaxis Treatment and Oral Antivirals
- Disposal of Extra Doses of Nirmatrelvir from Blister Packs for Patients with low eGF
- COVID-19 Therapeutics Information Resources

Sotrovimab is NO Longer Authorized to Treat COVID-19 in any U.S. Region

As of 04/05/2022, the FDA has updated the Sotrovimab Emergency Use Authorization stating **Sotrovimab is no longer authorized to treat COVID-19 in any U.S. region due to increases in the proportion of COVID-19 cases cases caused by the Omicron BA.2 sub-variant.** FDA will continue to monitor BA.2 in all U.S. regions and will provide follow-up communication when appropriate.

The Centers for Disease Control and Prevention (CDC) Nowcast data from April 5, 2022, estimates that the proportion of COVID-19 cases caused by the Omicron BA.2 variant is above 50% in all Health and Human Services (HHS) U.S. regions. Data included in the health care provider fact sheet show the authorized dose of sotrovimab is unlikely to be effective against the BA.2 sub-variant. Due to these data, sotrovimab is not authorized in any U.S. state or territory at this time.

Health care providers should use other approved or authorized products as they choose appropriate treatment options for patients. Currently authorized alternative treatments are available for distribution. These include, Paxlovid (an oral antiviral treatment) and molnupiravir (an alternative oral antiviral for patients for which Paxlovid is not appropriate or accessible). Additionally, bebtelovimab is an alternative monoclonal antibody therapy that is currently authorized and available for distribution. Based on similar in vitro assay data currently available, these products are likely to retain activity against the BA.2 variant.

Healthcare providers should review the Antiviral Resistance information in Section 15 of the authorized Fact Sheets for each monoclonal antibody and oral antiviral therapy available under an EUA for details regarding specific variants and resistance. Healthcare providers should also refer to the CDC website (https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-proportions.html) and information from state and local health authorities regarding reports of viral variants of importance in their region to guide treatment decisions.

Evusheld Fact Sheet Updated

April 1, 2022, the FDA updated the Evusheld (tixagevimab co-packaged with cilgavimab) fact sheet and frequently asked questions with updated dosing information for patients who had already received the previously authorized initial dose (150 mg of tixagevimab and 150 mg of cilgavimab). These patients should receive an additional Evusheld dose as soon as possible, with the dose based on the following criteria:

- If the patient received their initial dose less than or equal to 3 months ago, the patient should receive a dose of 150 mg of tixagevimab and 150 mg of cilgavimab.
- If the patient received their initial dose longer than 3 months ago, the patient should receive a dose of 300 mg of tixagevimab and 300 mg of cilgavimab.

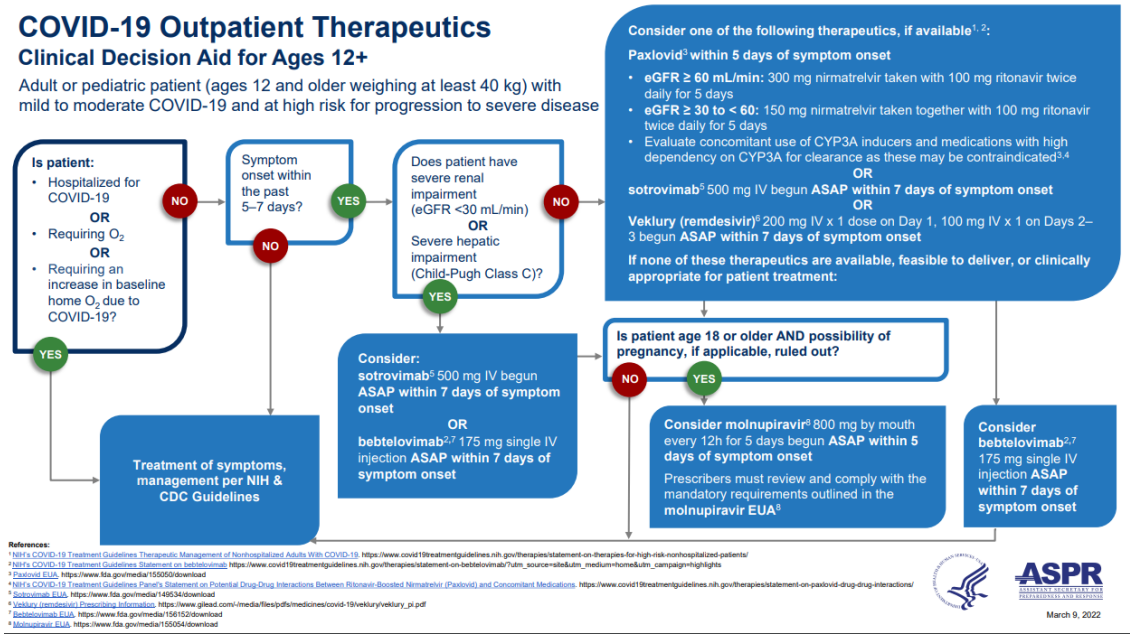
It is important to clinically monitor individuals for one hour following an injection of Evusheld. This guidance applies to patients returning for a booster dose. The FDA Fact Sheet for Healthcare Providers states, "*Clinically monitor individuals after injections and observe for at least 1 hour.*"

HRSA COVID-19 Uninsured Program and HRSA COVID-19 Coverage Assistance Fund

The HRSA Uninsured Program has stopped accepting claims for testing and treatment due to lack of sufficient funds. **Confirmation of receipt of a claim submission does not mean the claim will be paid.** Submitted claims will be paid subject to the availability of funds. No claims submitted after March 22, 2022 at 11:59 pm ET for **testing or treatment** will be processed for adjudication/payment.

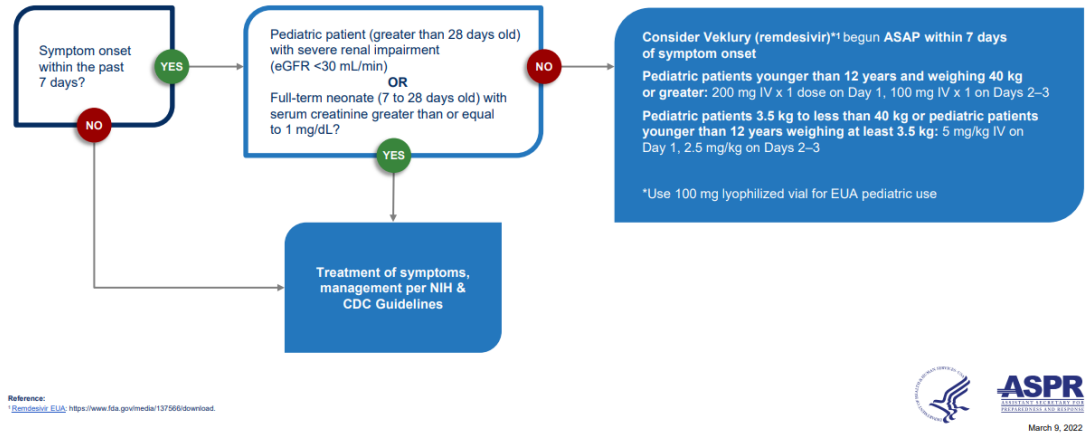
For additional information, see COVID-19 Uninsured Program Claims Submission Deadline FAQs.

COVID-19 Outpatient Therapeutics Clinical Decision Aids



Clinical Decision Aid for Pediatric Patients

Outpatient **3.5 kg to less than 40 kg** or **younger than 12 years of age weighing at least 3.5 kg**, with mild to moderate COVID-19 and at high risk for progression to severe disease



- COVID-19 Therapeutics Clinical Decision Aids

COVID-19 Test to Treat Locator

The Biden-Harris Administration launched a new nationwide Test to Treat initiative in March to give individuals an important way to quickly access free lifesaving treatment for COVID-19. The recently launched Test to Treat program supports this priority effort by creating an additional pathway for fast access to lifesaving COVID-19 treatments.

A **Test to Treat locator** is available to help find participating sites. A call center is also available at **1-800-232-0233** (TTY **1-888-720-7489**) to get help in English, Spanish, and more than 150 other languages – 8:00 am to midnight ET, 7 days a week. The **Disability Information and Access Line** (DIAL) is also available to specifically help people with disabilities access services. To get help, call **1-888-677-1199**, Monday-Friday from 9:00 am to 8:00 pm ET or email **DIAL@usaginganddisability.org**.

Molnupirair EUA Updated to a trade name Lagevrio

On 03/23/2022, FDA updated Merck's EUA to add references to Molnupiravir trade name as "Lagevrio". Corresponding revisions have been made to the authorized Fact Sheets which have also been revised to include updated antiviral activity and resistance information.

- Fact Sheet for Healthcare Providers
- Fact Sheet for Patients and Caregivers

Shelf Life Extension for Sotrovimab

GSK reports Sotrovimab doses with an expiration date of February 2022, have received a shelf life extension until August 2022. All other doses of sotrovimab have an 18 month shelf life. **All providers should check with the manufacturer prior to disposing of the product given the possibility of extended expiration dates.** After verification, expired doses should be disposed of in accordance with the facility's standard operating procedures on medication disposal.

Federally purchased sotrovimab is non-returnable to GSK. If healthcare providers purchased sotrovimab prior to the federal government securing doses, GSK has revised the returns policy during the EUA period. GSK will allow for returns for any reason subject to GSK's RGA process. For more information, contact GSK:

- www.gsk-ecs.com
- GSK Channel Customer Service Center: 800-877-1158, Option 4, Monday-Friday 8am to 6pm ET

GSK has also established a call center to assist healthcare providers in determining shelf life and expiration date.

- GSK Call Center: 1-866-GSK-COVID

Return of bam/ete and REGEN-COV NOT Recommended

Product return of bam/ete and REGEN-COV is ***NOT*** recommended as any returned product has to be destroyed. The COVID-19 environment remains dynamic and these products may be effective against future variants. Current supplies of bamlanivimab plus etesevimab and Regeneron's casirivimab plus imdevimab (REGEN-COV) should be retained by healthcare providers for potential use for other COVID variants. If healthcare providers have storage concerns or challenges, consider transferring products to another location/site in the region or health system.

If product must be returned, please follow the guidance below:

- Email the IDPH COVID-19 Therapeutics Call Center on the intent to return products
- For bam/ete, see The Lilly Return Goods Procedure; detailed guidance can be found at: https://www.trade.lilly.com/assets/pdf/lilly-product-return-procedure.pdf
- For REGEN-COV, call 844-734-6643
- Note: Reconstituted (diluted) product SHOULD NOT be returned and should be treated as waste per the facility's SOP

As doses of bam/ete expire, all providers should check with the manufacturer prior to disposing of the product given the possibility of extended expiration dates. After verification, expired doses should be disposed of in accordance with the facility's standard operating procedures on medication disposal.

Guidelines for Product Return

All therapeutic products are property of the United States Government and must be used in accordance with EUA guidance. Sites of care cannot donate products to entities outside the U.S. or for use outside the U.S. Any returned product will be destroyed, as product integrity cannot be verified. Non-expired products should not be destroyed. Any returned product needs to be quantified by the United States Government.

- Email the IDPH COVID-19 Therapeutics Call Center on the intent to return products
- Long-term utility of authorized mAb products is expected
- After consultation with the IDPH COVID-19 Therapeutics Call Center, if undamaged product needs to be returned, follow the below instructions:
    - For bam and bam/ete, see The Lilly Return Goods Procedure, detailed guidance can be found at: https://www.lillytrade.com/
    - For REGEN-COV, call 844-734-6643
    - Reconstituted (diluted) product SHOULD NOT be returned and should be treated as waste per the facility's standard operating procedures

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CMS Updates Codes for 600 mg Evusheld

CMS released the new product code updates for Evusheld.

- New product code for 600 mg dosing regimen of Evusheld (Q0221)

- Product code effective back to the date of the FDA EUA update (Feb 24, 2022)
- Original product code of Q0220 (300 mg) still effective and can be used for "catch-up" doses

Resources

- CMS COVID-19 Monoclonal Antibodies Toolkit

CMS Updates Codes for Bebtelovimab and Remdesivir

CMS released the following new codes for Bebtelovimab and Remdesivir effective February 11, 2022.

Q0222

- Long descriptor: Injection, bebtelovimab, 175 mg
- Short descriptor: Bebtelovimab 175

M0222

- Long Descriptor: IV injection, bebtelovimab, includes injection and post administration monitoring
- Short Descriptor: Bebtelovimab injection

M0223

- Long Descriptor: Intravenous injection, bebtelovimab, includes injection and post administration monitoring in the home or residence; this includes a beneficiary's home that has been made provider based to the hospital during the covid-19 public health emergency
- Short Descriptor: Bebtelovimab injection home

Resources

- CMS COVID-19 Monoclonal Antibodies Toolkit
- Updated FAQs – Payment/Coding for Veklury (Remdesivir) (Pg 146/Question 30)

Reporting Evusheld Doses in HPoP

Evusheld now should be administered as an initial dose of 600 mg. Individuals who already received the previously authorized initial 300 mg dose should receive a second Evusheld dose as soon as possible.

Reporting doses of Evusheld in HPoP: Healthcare providers are required to report on-hand and usage data of Evusheld **daily** in HPoP.

- Report on-hand inventory based on the number of 300 mg cartons.
- Healthcare providers should not edit Evusheld inventory in HPOP to account for the change in the initial dose. Regardless of the Evusheld dose(mg) administered, a carton or "dose" is 300 mg.
- The initial "dose" administered is 600mg or two 300mg cartons. For the purpose of reporting in HPoP, healthcare providers should report by numbers of cartons. Two cartons administered to a patient would be reported as two "doses" given.
- The catch up "dose" is 300mg or one carton. For the purpose of reporting in HPoP, report by numbers of cartons. One carton administered for a catch up dose would be reported as one "dose" given.

Evusheld Resources:

- Fact Sheet for Healthcare Providers
- Healthcare Provider Letter
- Fact Sheet for Patient's, Parents, and Caregivers

As part of the EUA, FDA requires health care providers who prescribe Evusheld to report all medication errors and serious adverse events considered to be potentially related to Evusheld through FDA's MedWatch Adverse Event Reporting program. Providers can complete and submit the report online; or download and complete the form, then submit it via fax at 1-800-FDA-0178.

Please contact C19therapeutics@idph.iowa.gov, with questions about HPoP.

Allocations Cadence Changes for Monoclonal Antibodies, PReP Treatment and Antivirals

Antivirals will shift to a weekly allocation cycle. This will align with the weekly allocation cadence for monoclonal antibodies (Bebtelovimab and sotrovimab) and the pre-exposure prophylaxis treatment (Evusheld). The ordering cadence will be as follows:

- Allocation Survey Sent - Monday
- Allocation Survey Due Back to IDPH - Tuesday at 4:00pm
- Allocation Ordered in Federal System - Thursday
- Allocation Amount Notification from IDPH to healthcare providers - Thursday

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Therapeutic Reporting Reminder

Sites receiving monoclonal antibodies, pre-exposure prophylaxis treatment, or oral antivirals MUST comply with federal reporting requirements.

Failure to comply with reporting requirements may result in the loss of COVID-19 therapeutic providers status and removal of COVID-19 therapeutic products. **Reporting requirements are as follows:**

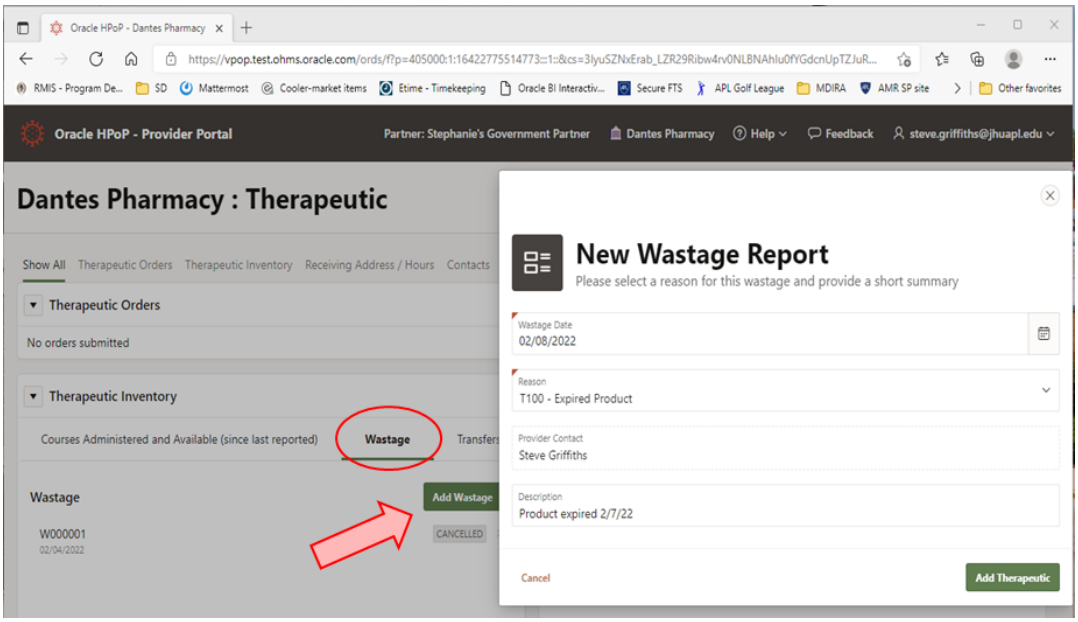
- Monoclonal antibodies (REGEN-COV, bamlanivimab/etesevimab, sotrovimab): Report on-hand and usage data **every Wednesday** in NHSN (for long-term care facilities) or Teletracking (for all other sites including hospitals).
- Pre-exposure prophylaxis treatment and oral antivirals (Evusheld, Paxlovid, Molnupiravir and Bebtelovimab): Report on-hand and usage data **daily** in HPoP. If you need assistance with HPoP, please contact C19therapeutics@idph.iowa.gov.

Reporting Wastage Guidance

In the Provider or Partner Portal, a new tab has been added in the Therapy Inventory section – Wastage. Wastage will be reported for all therapeutic products except Sotrovimab. The following steps outline the reporting of wastage of COVID-19 Therapeutics in HPoP:

- Choose wastage, then select the green "Add Wastage" button. A blank report appears.

- Enter the wastage date, the reason for the wastage (expired, damaged, temp excursion, or other).
    - A provider contact may be chosen, or is predetermined.
    - A description can be added.
- Upon selecting Add Therapeutic, a second window will open allowing details for each line in the wastage report to be entered. Select the therapeutic from drop down, enter the number of courses, a lot number and the lot expiration date.



Allocations Threshold Remaining for Monoclonal Antibodies, Pre-Exposure Prophylaxis Treatment and Antivirals

	Iowa Statewide Allocations Threshold Remaining for the week Monday, April 4, 2022 - Sunday, April 10, 2022		
mAbs	Oral AVs		PrEP
Bebtelovimab	Mulnupiravir (Lagevrio)	Paxlovid	EVUSHELD
115 courses	**0 courses**	**0 courses**	**1848 doses** (monthly allocation)

- The minimum order quantity for Molupiravir is 24 courses.
- **Allocations will not include sotrovimab, bamlanivimab plus etesevimab and casirivimab plus imdevimab (REGEN-COV).**
- **IDPH encourages entities who do receive allocations of therapeutic products to notify and work with prescribers and LPHAs on the availability of therapeutic products in the community.**
- The Department of Health and Human Services has released a COVID-19 Therapeutics locator.

Disposal of Extra Doses of Nirmatrelvir from Blister Packs for Patients with low eGFR

Per Dear HCP Letter endorsed by the FDA, in reference to moderate renal impairment dosing adjusted to 150 mg nirmatrelvir with 100 mg ritonavir taken twice daily for 5 days: "Pharmacists should discard the removed tablets per state requirements or local guidelines." It is recommended providers dispose of the medication via the workflows used to dispose of expired or other waste purposes. The HCP letter and Pharmacist Instructions are available at: https://www.covid19oralrx-hcp.com/resources

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COVID-19 Therapeutics Information Resources

- **COVID-19 Therapeutics Call Center -** IDPH has established a COVID-19 Therapeutics Call Center. To reach the COVID-19 Therapeutics Call Center, call **515-281-7317**.
- **COVID-19 Therapeutics Email -** IDPH has set up a COVID-19 Therapeutics Email to respond specifically to questions from healthcare providers regarding COVID-19 therapeutics. Therapeutic questions can be emailed to: C19Therapeutics@idph.iowa.gov
    - NOTE: **The COVID-19 Therapeutics Call Center and Email are intended for healthcare providers only.**
- **COVID-19 Therapeutics Table-** IDPH has developed a table of therapeutic products available for the treatment or prevention of COVID-19.